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Biotechnology assessment

Parliamentary technology assessment of biotechnologies: a review of major TA reports in the European Union and the USA

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Based on a review of some major technology assessment agencies dealing with biotechnology and bioethics in the USA and five countries of Europe, this study compares the approach in the different countries. It is found that the countries of Europe have less national differences than there are between the USA and Europe. The core concern in Europe has been to promote biotechnologies without meeting too much popular resistance. In Denmark and some other European countries the will to include citizens in technological debates has led to the setting up of consensus conferences, involving a lay panel which issues a report at the end of the process.

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THE EXPRESSION 'technology assessment' comes from the name of a former (1972–1995) support agency of the United States Congress. That agency enabled members of the legislative branch of the US Government to formulate policy with a better understanding of the issues, notably with respect to scientific and technological developments. The expression is a little inaccurate in that it does not do justice to the goal pursued by the founding fathers. Following the social movements of the 1960s, elected representatives wanted to improve the legislative branch's ability to understand scientific and technological issues, especially so that they could regain some of the authority Congress had lost to the executive branch.

Congress was seeking to improve its competence in every sense of the term. The decline of parliaments has been a recurrent theme in political science since the end of the first world war. From this point of view, the Act which established the Congressional Office of Technology Assessment in 1972 was not just about technology. It was a highly significant political event, whereby a legislative body attempted to recover power, through supplying its members with comprehensive means to master complexity and to express autonomous judgements. (The agency came to a halt in 1995 because of Congressional budgetary restrictions.)

The idea immediately drew interest in Europe as well. Similar organisations were put in place during the 1980s in France, the Netherlands, Denmark, Germany, the United Kingdom, and the European

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Parliament. Italy, Finland and Greece have joined the group quite recently, in 1996. The mere fact that the number of such technology assessment institutions has been growing suggests that a basic challenge of contemporary society is perceived in various places. Rapid advances of science and technology clearly have an impact on everyone's life.

However, how can we relate science and technology to politics and democracy? These issues seem to belong to completely different worlds, based on different values, different reward systems, different actors, different languages. While technology assessment is, explicitly or implicitly, expected to bridge the gap between those differences, the task may prove more difficult in practice than in theory.

A detailed history of the various institutions has been dealt with elsewhere (Bimber, 1996; Mironesco, 1997). One potentially interesting piece of information is still missing: there is no systematic research about the implementation of the assessment studies in the policy-making process, even though there is some evidence about the ways that legislators used the information produced by the agencies (Bimber, 1996, pages 25–40).

Nevertheless, assessment studies deserve attention: they express questions and answers formulated so far, in various countries, to take up serious challenges of contemporary politics. Is democracy affected by the growing power of experts? Is it influenced by a (hypothetical) decline of parliaments? What sort of message should be considered as objective, accurate, relevant information for elected representatives, in such a way that they will be more likely to make informed decisions? Studies illustrate tentative answers to these questions.

This paper is based on a review of some major technology assessment reports dealing with biotechnology and bioethics, published since the end of the 80s, in the United States and Europe. As far as Europe is concerned, the review will be limited to the five countries which are members of the European Parliamentary Technology Assessment (EPTA) network — Denmark, France, Germany, the Netherlands, and the UK — and to the assessment unit of the European Parliament which is also a member of that network.

The United States

> "OTA's role is neither to promote nor to discourage the development or the application of any particular technology or legislation, but rather to help Congress determine whether or when some form of Federal government participation may make sense. OTA identifies and clarifies options; exposes misleading, unsupportable, or incorrect information; and works to raise the level of understanding in the debate about expensive and controversial issues." (OTA, 1993a).

From the mid-80s on, OTA produced about ten reports on biotechnologies. The topics were broad and varied. They dealt with: commercial biotechnology in an international perspective; changing agriculture; basic research (Genome project); the dairy industry; biomedical laws and ethics. The best known reports, in the US and abroad, are probably a series which was published in 1987 and 1988, under the title *New Developments in Biotechnology*. Five volumes have been produced: *1. Ownership of Human Tissues and Cells* (OTA, 1987a); *2. Public Perceptions of Biotechnology* (OTA, 1987b); *3. Field-testing Engineered Organisms* (OTA, 1988a); *4. U.S. Investment in Biotechnology* (OTA, 1988b); *5. Patenting Life* (OTA, 1988c). By the beginning of the 90s, the US Congress was the most widely informed legislative body in the world, at least potentially.

If OTA's role was neither to promote nor to discourage the development or the application of any particular technology, what *was* its role? By declaring that it was limited to identifying options, providing accurate information, working to raise the level of understanding in the congressional debates, the agency adopted a modest tone to assert a not-so-modest mission. The decision-making role was left to congressmen, while impartiality was entrusted to analysts, who were supposed to be neutral in a highly partisan arena. The analysts strove to translate their knowledge to answer different or even contradictory questions, and to enlighten equally parties and committees having different interests.

Let us illustrate this with one report of *The New Developments in Biotechnology Series*. Our choice is not arbitrary, since this example was picked up by the congressmen themselves as a good report (OTA, 1993c). *Ownership of Human Tissues and Cells* (OTA, 1987a) deals with scientific, economic and legal issues. It begins by giving simple but clear definitions and explanations about the revolution in biological technology since the 70s. Three broad classes of basic technique are reviewed: tissue and cell culture; cell fusion to produce antibodies; and recombinant DNA.

However, the report is not designed to teach a course on biology. It tackles a novel and quite puzzling question: who owns human cells? The human source of the original tissues and cells? The scientist who developed the cell line? The firm (pharmaceutical, oil and chemical, agricultural ... companies) actively engaged in biotechnology research and commercial product development?

The argument unfolds along lines showing that there are indeed various human actors sharing an interest in dealing with such a question. This is the added value. As far as scientific and technical information is concerned, the report gives only the bare necessities. In fact, it is the rest of the text which is illuminating for politicians or citizens. The analysis presents disputes over ownership of tissues and cells, without taking sides; it lays out detailed arguments in favour or against specific answers.

The end result of the story told in *Ownership* is to bring biotechnology back down to earth. The reader realises that the issue may be very mundane, that it is possible to debate and take decisions about it without having a PhD in biology, that the problem is at the same time new and old, as issues relating to ownership and property have been part of the political agenda for ages.

Another aspect that should be underlined is that the procedure is meant to clarify choices for elected representatives, not to solve problems on their behalf. *Ownership* has been criticised on the grounds that the basic question asked by the report is not answerable by analysis; OTA was therefore guilty of asking wrong questions (Woodhouse, 1992, pages 23–24). This is an unfair comment and a rather unsafe misconception. OTA did ask a good question, philosophically speaking. It did not answer it, because it considers that answers (that is, choices, decisions) belong to elected legislators, after they have been properly informed.

Such a division of work between legislators and analysts became apparent, to a certain extent, in bioethics as well. OTA's *Biomedical Ethics in U.S. Public Policy* appeared in 1993 as a background paper (OTA, 1993b). Its distinctive feature was the secular tone adopted all along. It started from "the need to bring the perceived chaos of biology and medicine into the order of principle" (OTA, 1993b, page 2).

OTA's conviction was that bioethics is a field that involves professionals of many backgrounds (philosophers, theologians, attorneys, clinicians, researchers ...). No one individual or profession can represent the breadth of perspectives on the topic. Bioethics was clearly not understood as a new specialisation, or a new scientific and technical development that should be explained to uninitiated congressmen or citizens. What was the assessment function in that context?

The study was conducted to "assist Congress in determining possible approaches to examine policy problems with biomedical and ethical dimensions" (OTA, 1993b, page 3). More specifically, Congress was supposed to decide at some point whether or not to create a new Federal bioethics body. The request sought to obtain clarification about options, from that point of view. This is why the study was, in fact, a review of the history of previous broad-based Federal bioethics initiatives. Four of these were reviewed: two were located in the Department of Health, Education and Welfare; a third was an independent executive branch commission (the President's Commission for the Study of Ethical Problems); the fourth was located in Congress. None had survived very long (two to four years).

The US Office of Technology Assessment's job was practical and down to earth: to analyse the reasons for success or failure of previous trials — it never tackled issues of finding moral solutions to complex policy matters

OTA's job was practical and down-to-earth: to analyse the reasons for success or failure of such trials. It never tackled issues of finding moral solutions to complex policy matters. Requesters and analysts were engaged in striving to learn lessons, as objectively as possible, from past experience. They were involved, so to speak, in a process of self-analysis. In addition, OTA's study was meant to learn lessons from abroad. The appendix is a catalogue of international bioethics initiatives. In 1992, OTA conducted a survey of bioethics and related individuals in government offices, in 35 countries.

This fact-finding thought process, combined with a search for self-analysis and self-reliance, contributed a lot to the secular tone of the approach. Actually, the approach did not appear in the 90s as if by magic. Growing awareness of the human capacity to influence living processes had aroused emotions, on both sides of the Atlantic, at the end of the 70s.

In the United States, a secular authority appeared quickly in the foreground, with regard to the debate over the granting of patents to genetically engineered organisms. In 1980, the Supreme Court decided in *Diamond v. Chakrabarty* that those organisms were indeed patentable (Plein and Webber, 1992, pages 135–139).

The question was not: is patenting life morally acceptable? but: is it constitutional? This is self-analysis, again. The Supreme Court's argument was that the US Constitution is meant to protect human ingenuity, ant that "although laws of nature, physical phenomena, and abstract ideas are not patentable, Chakrabarty's micro-organism was a product of human ingenuity" (OTA, 1988d, page 8).

This was a public and authoritative recognition that human knowledge had reached a turning point. By doing so, the Supreme Court also emphasised Congress' responsibility for dealing with those issues. The division of power and the secular approach seem to belong to the same culture. This process was also described at length in the 1988 report *Patenting Life* (OTA, 1988c).

European Union technology assessment

Not every member state of the European Union is equipped with a special agency of technology assessment. Taken in chronological order of creation, those that exist are:

- the French Office Parlementaire d'Evaluation des Choix Scientifiques et Technologiques, OPECST (1983);

- the Dutch Netherlands Organisation for Technology Assessment, NOTA, now the Rathenau Institute (1986);
- the Danish Teknologinaevnet, now Teknologiradet (1987);
- the British Parliamentary Office of Science and Technology, POST (1987); and
- the German Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, TAB (1989).

These agencies are loosely co-ordinated in the European Parliamentary Technology Assessment (EPTA) network, created in 1990. Also a member of the network, the European Parliament's Scientific and Technological Options Assessment (STOA) programme was created in 1987.

Denmark

The Danish Board (now Council) of Technology (DBT) has been involved in various activities in the biotechnologies. From 1987 to 1992, it administered the TA part of the Danish research and development biotech programme. It adopted a pluralistic strategy and produced videos, books, reports, booklets aimed at different target groups and parties.

It collaborated with trade unions on a project in which workers from various branches of industry assessed the impact of biotechnologies on working life. It conducted surveys on public opinion. It reviewed literature and interviewed opinion makers and central actors in the debate on ethical aspects in USA, Germany and England. It also organised consensus conferences (DBT, 1993). The following are some detailed examples.

National research capacity

In 1991, the Board reported on *Research and Development in Danish Biotechnology*. This evaluation of the national research capacity focuses on "new biotechnology", that is, derived from molecular biotechnology (recombinant DNA-techniques, cell fusion, cell and tissues cultures). It deals with the question: what is the balance between capacity and needs? Three quarters of the biotechnological research capacity is located in the private sector, one quarter belongs to the public sector, which concentrates on basic rather than applied research. As far as needs are concerned, the project underlines that research is too limited in plant and animal techniques, in relationship to environmental problems, or in areas of special interest for developing countries.

From this, the report concludes that Denmark should specialise, in order to be competitive on the international scene. It should provide for new business activities, mainly in environmental protection and/or in response to the demands of developing countries. Too little is known about how to use recombinant DNA to produce cleaner technologies, and progress can be made in vaccine and plant research as well. This is how Danish research could participate in international co-operation more efficiently (DBT, 1991).

Environment

One year later, the Board reported on *Biotechnology in the Environmental Field*. The project had several objectives: to evaluate major environmental problems, but also to assess legislative problems related to the use of biotechnologies in Denmark; to review literature and to interview specialists on how biotechnology may be viewed as a green technology; to look for possible ways of promoting such a technology in the country.

The analysis deals first with an overview of how biological techniques could be helpful in cases of air, water and soil pollution. It then underlines that air pollution, caused by energy production and traffic, will not be easily solved; in addition, the three types of pollution are of a local nature, and therefore national initiatives may not seem very convincing.

Nevertheless, there are some areas of interest, one of which is agribusiness. Pesticides, fertilisers, manure and so on are sources of pollution: environmentally suitable production may be developed, based on, for instance, microbial crop spray and biotechnological crop improvement. Another field for progress is waste water: here the effort should be better co-ordinated. In soil treatment, microbiological degradation of harmful substances is supposed to be an inexpensive and environmentally friendly method (DBT, 1992a).

Consensus conferences

The Board did not deal with research and development only. Within the European parliamentary TA network, it is mostly famous for having formalised debates involving ordinary citizens in the assessment process. The debates are called consensus conferences and take place between a panel of experts and a panel of lay people (about 10–15 people in each panel). The lay panel is neither representative of the entire population, nor of the Danish Parliament. It is selected by the Board, according to criteria such as age, sex, place of residence, occupation and educational background.

At the end of the sessions, the lay panel is expected to report its views publicly. The Parliament may then take them into account. The Board has arranged consensus conferences on key topics. The following are detailed examples.

In April 1987, a conference was held, in co-operation with the Society of Danish Biologists, on Genetic Technology in Industry and Agriculture. The lay panel presented its conclusions in a short document. It stressed that genetic engineering is very different from traditional biotechnology as it was practised formerly in agriculture and industry: it is

now possible to combine genes across the natural species barrier, endangering or weakening the natural evolution.

Danish lay people believe that this challenges the ethics; they wonder whether human beings, as part of the created world, have an unconditional right to intervene in it. A majority of the panel accepts genetic engineering, provided that it is strictly controlled and designed to be a service for mankind. A minority wants it to be completely banned.

The whole panel agrees to prohibit genetic engineering on animals. They also consider that research on risks is inadequate and should be improved. They finally suggest the creation of an ethical council consisting of lay people only; they express their hopes for an independent information programme to help citizens to understand those issues better; they call for a more critical attitude towards industry which must be held responsible for any hazardous consequences of its products (DBT, 1987).

In November 1989, another consensus conference was held in co-operation with the Research Committee of the Danish Parliament. The topic was the Application of Knowledge gained from Mapping the Human Genome. To begin with, the Board reminded the panel that mapping the human genome has become a scientific goal all over the world, and that the United States and Japan have launched large-scale programmes on the subject. In addition, the European Union Council of Ministers is considering a proposal from the European Commission about a joint European programme, as an answer by the Union to the large foreign projects.

The end result of this international research should be an increased quantity of information about risks and dispositions for diseases, gene profiles, prenatal diagnosis, screening of the adult population, crime-solving, and so on. The question asked of the Danish lay panel was therefore: how should we use the increased knowledge about human genes? (DBT, 1989, page 2).

Generally speaking, the panel approves of knowledge used to cure diseases. Nevertheless, a majority has strong reservations about systematically screening the population which will only result in causing fear and anxiety. They ask for the establishment of a tribunal to provide politicians with advice. They recommend the drafting of a list indicating for what kind of genetic aberration prenatal diagnosis should be possible. The panel fears the risk of eugenics, in so far as people might want to be tested for illnesses that are not serious; they want a popular debate on the meaning of 'normality'.

On the other hand, the panel recommends legislation to forbid genetic analysis from becoming the basis for the assessment of a person, be it in relationship to employment, insurance or retirement. As far as the scientific prestige of the project is concerned, the panel is convinced that human genome analysis can result in important developments, but they insist that it is developed in harmony with the ethical and cultural values of the population. This is why the information level and the popular debate must be strengthened. Finally, the panel feels that basic research should focus on improving knowledge about the interaction between heredity and environment (DBT, 1989, pages 5–7).

When releasing technological animals into nature, extensive risk analyses must be performed; the long-term consequences of consuming food produced by such animals are not well known, so labelling these food products is a reasonable demand

In September 1992, the Board arranged a consensus conference, in collaboration with the Research Committee of the Danish Parliament, on Technological Animals. This title refers to the product of techniques interfering with the gametes or the embryo of an animal. First of all, information was provided to the lay panel. Technological animals may be used in the agricultural, fishing or pharmaceutical industry; they may also be used for research purposes. They contribute to a field of biotechnology which is becoming increasingly important. However, the public attitude to this field has been rather negative. The conference was meant to diffuse interest and knowledge, and to stimulate public debate on the topic.

The lay panel concluded that interest groups and ordinary citizens should, to a greater extent, be represented in councils and boards where regulations are being established, and that they should all have access to information. As far as the economy is concerned, the panel recognises that it may be unavoidable to pay a licence fee (for instance, to cover the cost of research) and that the fees may have a negative impact on products costs; a possible alternative is to increase research and development in ecological farming.

In relation to patents, though, the lay panel underlines that the Danish Parliament has already decided to prohibit the patenting of animals: considering that patenting life is not acceptable, the panel agrees with Parliament's decision and wants it to be promoted in international negotiations. When releasing technological animals into nature, it is necessary to perform extensive risk analyses. In the same vein, since the long-term consequences of consuming food produced by technological animals are not very well known, labelling those food products is a reasonable demand.

With respect to ethics and values, the panel wishes to make sure that animals do not suffer and that researchers take animal welfare into account. If alternative methods are available, these should always be preferred, although it seems reasonable and ethically acceptable to produce technological animals to try to cure serious diseases, such as cancer (DBT, 1992b).

As far as the political impact of these consensus conferences is concerned, as a consequence of the 1987 conference, the Danish Parliament decided not to fund animal gene technology projects in the biotechnology research and development programme 1987–1990. The same Parliament decided to forbid the use of genetic testing for recruitment and insurance claims, as a consequence of the 1989 conference (Klüver, 1995, page 44).

The Netherlands

The Dutch TA agency, formerly designated by the acronym NOTA, became the Rathenau Institute in 1994. With respect to biotechnologies, this agency interprets its mission in terms of both discussion promoter and information provider. When NOTA was founded, in 1986, its task was "to draft and to realise a programme of technology assessment research"; it was also aimed at providing the Minister of Education and Sciences with advice on matters relating to the integration of science and technology in society.

Its relationship to Parliament was indirect; it was not clear, in the original charter, that NOTA should focus its work on the legislative body. At the beginning of the 90s, there was a consensus to stay at a certain distance from the Parliament (Sterrenberg, 1993a). Nevertheless, studies also display information or policy options for the Dutch Parliament.

Engineered organisms

In 1988, NOTA and the Dutch Ministry of Economic Affairs organised workshops on the introduction of genetically engineered organisms into the environment. One of these was based on the *Field-testing Engineered Organisms* report published by the American OTA (1988a). The participants in the various debates were government representatives, representatives of industry and of biotechnological research, and representatives of so-called "societal groups" (such as farmers and consumers).

The experiments led the NOTA to conclude that members of organisations with divergent interests tend to have different interpretations of the term 'risk'. Nevertheless, the confrontation of different actors did not lead to a polarisation of standpoints, as some people of industry had feared. At that point, the workshops did not have any influence on parliamentary decision-making about regulations; political interest in the subject was low (European Congress on Technology Assessment, 1992, pages 263–272).

Genetic engineering on animals

At the beginning of the 90s, NOTA dealt with another issue at great length: the genetic engineering on animals. This subject had given rise to various controversies. The agency had noticed that there was no consensus on the conditions that should be met for this technology to be accepted. On the other hand, progress in this area was rapid; reflection and debate were urgent.

In 1990, a publication dealt with *Ethics and genetically modified animals* (NOTA, 1990). The authors tackled two questions: is the issue really new? is it morally acceptable? While it was admitted that humanity's use of animals is not something new, the authors also underlined that today's technology makes it possible to take the genetic material from one species and transplant it into another. Life processes appear therefore to be programmable by humanity in an unprecedented way.

There is no consensus as to the acceptability of such a development. Some people tend to accept genetic engineering without any restrictions, some would reject it on principle, while still others would accept it under certain conditions. To assess the ethical acceptability of genetic engineering on animals, the authors suggest first admitting that animals have an "intrinsic value", and then to answer questions such as: does the aim justify an infringement of the intrinsic value? is the aim likely to be achieved? are there any alternatives for achieving the same aim? (NOTA, 1990, pages 117–120).

A part of the publication also discussed how and to what extent the government can include ethical considerations in its policy. It was stated that both *laissez faire* and ideological interference were to be avoided. To get more insight on that topic in the near future, a research agenda based on a number of ethical questions was set up a little later (Sterrenberg, 1993b).

Environment

In 1991, NOTA dealt with the introduction of *Genetically Modified Organisms in the Environment.* In fact, this working document presented the results of interviews with different people (researchers, legislators, businessmen, farmers, environmentalists, church and consumers groups) about a specific experiment. From their reactions, NOTA drew up a set of questions which may be relevant for official approval procedures. Because a large part of the discussion dealt with ethics, values and priorities, NOTA underlined that "skills which are necessary for a discussion about moral questions require extra attention" (NOTA, 1991b, 135).

Patentable animals

In 1991, NOTA (1991a) also prepared a report on *Patentable Animals* for Parliament. The issue had become important since 1988, when the European Commission launched a draft directive for the legal protection of biotechnological inventions, including animal material. The European Patent Convention of 1973, ratified by ten European member states including the Netherlands, excluded varieties of animals from patents (although patents were granted on

micro-organisms, micro-biological methods and animal and cell lines in the production of medicines and vaccines).

In fact, the European Patent Convention was open to more than one interpretation. By introducing the draft directive, the European Commission wanted to reach a consistent policy on patent granting and harmonise national legislation. The directive was also justified on the grounds of the competition between biotechnology industries in the European Union, the United States and Japan (NOTA, 1991a, pages 55–56).

The Netherlands Industrial and Agriculture Biotechnology Association was of the opinion that the European directive did not go far enough. Other groups (consumers, farmers, environmentalists) felt that it went too far. Their main objections were: there had been no debate on the ethical acceptability of these inventions; there might be an increase in the livestock farmer's dependence on trade and industry; it might lead to a further decline in the genetic diversity of livestock; it could have negative effects on developing countries, unless intellectual property is well protected in the developing country itself; and it may have a limiting effect on research. After having reviewed these various arguments, NOTA concluded that there are three options open to Parliament (NOTA 1991a, pages 58–59):

- to adopt the draft directive (which would help to harmonise national legislation);
- to reject it (which would block consistent legislation);
- to amend it, accommodating those aspects that have aroused criticism.

In 1992, NOTA continued with this difficult dilemma of facing both international competition and national lack of consensus. First, the agency prepared a comparative study about legislation and regulations on the genetic modifications of animals. It reviewed the situation in the European Commission, the Netherlands, the United Kingdom, Germany, Denmark, France and the USA. It underlined differences among countries, but also similarities among Denmark, Germany and the Netherlands, which all three appeared to be more reluctant with regard to genetic modifications of animals, when modifications are aimed at the production of meat and milk rather than at the production of medicines (NOTA 1992a).

Second, NOTA tackled the issue of understanding the most important ethical and legal aspects for government policy. It defines ethics as "the philosophical scientific discipline which systematically studies ethical aspects, norms and values". The report then goes on to state that the analysis of emotions is of significance for government. In cases of conflicts, the government would have three options: to delegate ethical decisions to an ethics committee (proceduralism); to settle the conflict by adopting the principle of majority (democratism); to emphasise the right of freedom of its citizens (liberalism) (NOTA, 1992b).

Last, but not least, the agency published a study on biotechnology and small-scale farmers in developing countries. The question which motivated the study was how to improve those farmers' situation. Although biotechnology had a strong potential for that purpose, traditional technology transfer was considered less helpful than an "interactive bottom-up" approach including small farmers in the process from the very beginning (NOTA, 1992c).

In 1993, NOTA adopted the Danish method and held a consensus conference (called "public debate") on the subject of genetic modification of animals. This was organised in collaboration with a private institute for consumer research, and an institution promoting the public understanding of science and technology and funded by the Dutch Ministry of Science and Education and the Ministry of Economic Affairs. The main conclusions of the debate were (NOTA, 1993a):

- a majority of the lay panel would like a moratorium on the genetic modification of animals;
- they think that lay people should be consulted more often;
- they call on the Ministry of Economic Affairs to have a "more critical–ethical" policy;
- they would like alternative technologies to be promoted.

During the same year, NOTA prepared a report for Parliament. It recalled that there are still diverging attitudes in the country with regard to the acceptability of genetic modification, and that various social groups are exerting pressures on politicians and government. The report stated that government should avoid both ideological interference and moral indifference, which would not do justice to the public concern (NOTA, 1993b).

Change of name

In 1994, NOTA changed its name to the Rathenau Institute. Its stated mission was clearly (Rathenau Institute, 1995a, page 9):

> "to contribute to the social debate and political opinion forming on issues that are the result of, or are concerned with, scientific and technological developments, including the ethical aspects of these developments."

Another aspect of its mission was (Rathenau Institute, 1994, page 33):

> "to stimulate the learning process in order to integrate social considerations into the development and selection process of products ... the results should form the basis for the formulation of specific points for the biotechnology policy

of the Ministry of Economic Affairs and the Ministry of Agriculture, Natural Resources and Fisheries.".

Where are we going?

In 1995, the Institute organised a public debate (a consensus conference) on Predictive genetic research, where are we going? in collaboration with the Platform for Science and Ethics, an official forum for organising debates on science and technology (Mayer *et al*, 1995). The lay panel admitted that predictive genetic research may provide solutions to human suffering, but it insisted on limiting it all the same: it wanted to avoid excessive diagnostic and medical techniques, fearing that these techniques might determine whether someone is perceived as healthy or not. The panel also would like to see ethics and ethicists more actively involved in the development of the research; it even called on a control, by ethicists and central government, on fundamental genetic research (Rathenau Institute, 1995b). Without clearly defining who ethicists are and what is the basis for the legitimacy of their decisions, the lay panel seemed to express somewhat authoritarian views.

At the same time, the Institute was busy adapting an important European concept: Constructive Technology Assessment (CTA). Two reports appeared in 1995. *Learning to Innovate* (Rathenau Institute, 1995c) was submitted to Parliament and dealt with the idea that technological development should be guided. So did *Biotechnology in Business. A Contribution of Constructive Technology Assessment to Biotechnological Innovation* (Rathenau Institute, 1995d). Both reports tackled the issue of social acceptance of genetic research applications, discussed the theme of "societal embedding" of the new biotechnology, and discussed the roles of government and parliament in preparing the market for biotechnological products (for example, by initiating dialogue with social organisations at an early stage).

Germany

Germany shared a special feature with Denmark and the Netherlands. Eurobarometers, that is, Union-wide surveys of public opinion, had shown all through the 80s that risk perception increases as one goes from south to north. The attitude of the German public towards biotechnology was rather critical; at the same time, the level of its knowledge seemed quite high (Science Museum, 1992). As the Dutch TA agency underlined in one of its recent reports (NOTA 1992a, 36):

> "compared to the French or to the English, the Germans showed more inclination to think that biotechnological research and especially gene technological research should be supervised by the government; in the German Parliament, this critical attitude was defended by the Greens and the Social-Democrats, at least in the eighties."

In Germany, the executive and legislative branches had shown concern for biotechnologies all through the 80s: hearings were conducted with domestic and foreign experts on issues such as scientific, technical, environmental and social risks

In fact, both the executive and legislative branches had already shown concern for biotechnologies all through the 80s. Hearings were conducted with domestic and foreign experts on issues such as scientific, technical, environmental and social risks. In 1987, a Commission of Inquiry (Chances and Risks of Genetic Engineering) of the Parliament recommended that safety guidelines were made legally binding. A legislation process started in 1989, and a German Gene Law was adopted in May 1990 (Gloede, 1997).

Safety

At the beginning of the 90s, a TAB study was conducted on Biological Safety in the Use of Genetic Engineering (cited in Gloede, 1992). This report contains the findings of an international comparison on regulation practices. Although a Gene Law had been passed in May 1990, providing for substantial and procedural measures to ensure biological safety in research and commercial activities, there were good reasons for the study to be made. The Commission of Inquiry, appointed by the Bundestag in 1984, had already dealt with safety guidelines for genetic engineering, but the members of the Commission knew that the topic was still important in the public controversy.

The question of the proper 'safety philosophy' in the assessment of the risks had remained largely unresolved. So had the issue of the social acceptability of these new techniques. When the study began in 1990, biological safety was criticised as being too narrow by both advocates and opponents of genetic engineering. The advocates wanted to underline the benefits, and not only the risks, of the new biotechnologies; while the opponents wished to stress potential social and political effects or risks (Gloede, 1992, page 275).

In 1992, an interim report was discussed. Its scientific basis was questioned, mainly with respect to the views expressed by the representatives of the ecological risk concept; those views were considered rather untrustworthy, given the context of international scientific discussion (note that, since the 1990 election,

the Greens were no longer represented in the Bundestag). At the same time, and more generally, the German Gene Law was criticised as potentially threatening the role of Germany as a leading country for science and industry: there was no lack, but an excess, of regulation, said the critics.

According to one analyst, the TAB study on biological safety was different from other TA studies (Gloede, 1992, page 276):

> "it is not simply aimed at enlightening decision-makers and the public by compiling and if necessary popularising available knowledge in a study. It rather proceeds from the existence of a multi-layered controversy on the topic and attempts to identify areas of both consensus and dissent, and also to describe alternative options for the legislative."

This effort, however, was not totally successful, insofar as communication between groups holding diverging views was sometimes very difficult indeed. Scientists (especially molecular biologists) tended to interpret controversies in terms of incompetence; politicians, in terms of impracticability; and for other antagonistic social groups, the whole TA process appeared illegitimate, endangering their interest or moral standards (Gloede, 1992, page 276). The final report on safety was published in 1993: it discussed options for the organisation of safety research and for legal regulation (Gloede, 1997).

Genetic mapping

Parallel to this analysis on safety, TAB conducted a study on Genetic Mapping — Opportunities and Risks of Genetic Diagnostics. The report was published in 1993 (TAB, 1993a). It recommended legal regulation in fields such as: criminal justice, health and life insurance, employees and places of work, health system. However, the recommendations have not been followed by legislative decisions so far. A monitoring process on gene therapy has been set up (Gloede, 1997).

As a reaction to the controversies which were still going on, the Committee for Research, Technology and TA wished to expand the TAB inquiry. The agency was given the mission to monitor trends in the TA landscape. One report was completed in July 1993 (TAB, 1993b). It is an interesting review and evaluation of selected foreign parliamentary TA studies.

With respect to new biotechnologies, the report underlines first that technology assessment agencies have been most active in Germany, Denmark, the Netherlands and the United States. A majority of studies deal with the application of biotechnology in general, or with its application to agriculture, or with its application to humanity (health, criminal law, gene mapping); a few studies deal with its possible application to the environment. The TAB analysts selected: an OTA report on global economy; a Dutch report, a Danish one, and an American one on agriculture; a POST report and an OTA report on patenting DNA, a NOTA report and a STOA one on bioethics (TAB, 1993, pages 1–3).

The TAB review of those various studies gave a good overall picture of the situation. The issue of commercial biotechnology and its fields of application appear as key issues for the years to come. The health sector opens a large market for this new technology, and so does the need for pharmaceutical products; in addition, in most countries, public acceptance is fairly high with regards to using biotechnology for improving diagnoses, therapies and health.

Applications to agriculture and food production are still in the development stage. Besides, some applications have been strongly criticised, namely by consumers associations. Nevertheless, the potential for quality improvement in that field should not be underestimated, even though special attention should be given to the delicate situation of small farmers and of developing countries. Likewise, applications of genetic engineering seem still very limited for the moment, and the issue of genetically modified organisms raises problems of social acceptance in many places (TAB, 1993, page 39).

As far as the international economy was concerned, the TAB report made things quite clear. It underlined that Europe is likely to face hard competition with the United States and Japan: the regulation climate is indeed quite restrictive on the 'Old Continent', especially in northern Europe and Germany, and it is marked by uncertainty. Intellectual property and patents are key factors in the development of commercial biotechnologies. In some countries (such as USA), patent protection is rather extensive. Harmonising international regulations will become a pressing need, in view of both commercial exchanges and scientific collaboration (for instance, in the framework of the Human Genome Project) (TAB, 1993, page 40).

Finally, the TAB report tackled the question of the risks and consequences of new biotechnologies. Although risks are mentioned quite often in debates, the authors noted that very little is known as to what those risks really are. Nevertheless, various applications of genetic engineering have been judged as dangerous from the ethical point of view. In a similar vein, critical opinions have been expressed by groups, in northern and central Europe. In this case, the difference is striking with the United States, Southeast Asia or southern Europe where public perceptions are more positive on the whole, especially when genetic engineering is aimed at health improvement (TAB, 1993, page 41).

Health issues

At the same time, TAB got actively involved in health issues. Two reports dealt with monitoring gene therapy. The first was published in 1993 (TAB, 1993c) and explained the scientific and medical state-of-the-art in the development of genetic therapeutic

methods. On the one hand, this development gave rise to great expectations with respect to the treatment of serious diseases (such as cancer and AIDS). On the other hand, the risks of those methods for the patients are not very well known yet.

The TAB report described the gene transfer process. It then went on to summarise the controversies that had taken place about the dangers of the process, and the current opinions of the German specialists, classified into four groups (from those who prefer viral vectors for a rapid development of genetic therapy, to those who are against any method, for safety reasons, except in cases of diseases which have no alternative treatment) (TAB, 1993c).

The whole exercise was meant to help the members of the Bundestag to bring in legislation to that field. As promised at the end of the first report, TAB published a second analysis in 1996, focusing on legislation and regulations abroad (TAB, 1996). It reviewed the situation at length in France, the United States, the United Kingdom, the Netherlands, Italy, Austria, and to a lesser degree, in smaller European countries and Japan. It indicated that the patients' safety and the biological safety were taken quite seriously everywhere.

The analysts found various tentative solutions in those countries, dealing with potential safety problems: severe criteria for applications of gene therapy; ethics committee to be consulted; regulations (with respect to clinical research, to cost–benefit analysis, to patient enlightenment and free consent, to public and penal liability). The report also drew the reader's attention to the European dimension of the issue, and to the need for the Union to be more innovative in that field (TAB, 1996).

Developing countries

TAB tackled another question at great length recently. In 1995, a report was published on the effects of modern biotechnologies on developing countries and consequences for the future collaboration between industry and developing countries (TAB, 1995). The project was initiated in February 1994 by the Committee for Economic Collaboration and the Committee for Education, Research, Technology and Technology Assessment of the Bundestag. Its overall objective was fairly ambitious: to examine how new biotechnologies could contribute to solving some problems of the developing countries, or to examine at least how the gulf between rich and poor countries could be stopped from widening.

The analysts first drew up a list of fields of application for biotechnological research: agriculture and food production (Germany had already promoted more than 100 research projects of that kind between 1988 and 1994); health; resources protection; and conservation. The report then went on to examine the case of developing countries in the international context. It finally indicated options for politicians interested in dealing with third world questions.

Three issues have been singled out, one of which was intellectual property and patent regulations. It was suggested that positive impulses should be given to developing countries, in the spirit of an argument developed by some international third world groups: it should be made possible to protect the indigenous knowledge of medicine or food production. The second and third issues were biological safety and genetic resources; both were in need of an international protection concept. In conclusion, biotechnologies could have potential positive effects on developing countries, provided they were adapted (for instance, oriented to the needs of small farmers, the promotion of local research, or the promotion of women and their contribution to innovation) (TAB, 1995).

United Kingdom

Since the beginning of the 90s, POST has prepared various studies and notes with regard to biotechnology. Patenting was one of the first important issues. It was dealt with in two steps: one study focused on patenting life, generally speaking; another tackled the patenting human DNA.

Patenting

Patenting Life (POST, 1991) seemed to handle the issue differently from the way it was handled in Denmark and the Netherlands. POST avoided taking sides in the ethical debate, but it gave as much information as possible to let Members of Parliament make their own judgement. The briefing note was especially worthy of comment: its conciseness made the message altogether enlightening for Members or for any citizen interested in those matters.

The note briefly explained the developments which have led to issues relevant for legislators. It first summarised the scientific aspects, simply and clearly, about how recombinant DNA technology can modify the basic genetic makeup of a living organism. It described the key steps in genetic modification and indicated the patentable ones (gene identification and isolation, identification and isolation method development, transfer of gene construct into living organism).

The report reviewed the patent laws in various countries; it showed differences, but also some similarities (all countries require that inventions demonstrate the characteristics of novelty, inventiveness and utility); in addition, the readers were informed that the European Commission had prepared a draft directive which would facilitate the patenting of genetically modified plants and animals.

The analysis then went on to explain current controversies. From a legal and/or scientific point of view, debates focused on: how far a patent can be applied to whole organisms; how far genetic engineering can be considered as an inventive activity (demonstrating novelty, and so on) since gene transfer may be perceived as a natural occurrence; how far

American policy-makers argued that investment of public funds should lead to products and services to benefit the USA: the quarrel has undermined the spirit of international scientific collaboration which was the basis of the human genome project

intellectual property protection, in that field, should be broad or restricted. From a religious and/or moral point of view, patenting is sometimes criticised as being equal to granting ownership of life forms, which either should not be considered as available for appropriation and exploitation, or should be viewed as the common heritage of humankind (POST, 1991). It is noticeable that POST's style was to present a balanced view of the pros and cons, and to describe controversies without arbitrating on them.

POST dealt with *Patenting Human DNA* a little later (POST, 1992). The report first explained that the problem had arisen within the context of a large international programme of scientific collaboration, aimed at decoding the human genome. The international programme is composed of a number of national programmes, primarily in the USA, France, Germany, Japan and the UK; the European Union too partly supports European researchers. Co-ordination between the programmes is assisted by the Human Genome Organisation (HUGO), which was established at the end of the 80s and consists of 500 research groups. Decoding the human genome is an enormous enterprise, with potential consequences for both commercial development and scientific understanding of gene functions.

POST had good reasons to deal with patenting life and patenting human DNA in two different steps. There had been controversies with respect to both issues, but the meanings and the stakes were not quite similar. In the human DNA case, there was a potential conflict between advancing scientific knowledge through international collaboration and protecting national economic interests.

American policy-makers did not want knowledge-producing projects to be easily commercialised by other countries. They argued that investment of public funds should lead to new products and services to the benefit of the USA; this is why the US National Institute of Health claimed, in 1991, to deposit patent applications for the basic data from their DNA programme. The previous practice of publishing partial sequence data was seen as a threat to the patentability of whole genes in the future. It was therefore a threat to companies' investment to explore potential applications of the new knowledge.

This attitude had been opposed by scientists outside the USA, and by many inside as well. An important argument of the opposition was that this approach was unprecedented because it attempted to patent sequences of genes or parts of genes, whose functions have not been identified. French scientists have also argued that the basic sequence of human DNA is part of the scientific heritage of humankind; therefore it cannot be appropriated by anyone.

The quarrel has already undermined the spirit of international scientific collaboration which was the basis of the human genome project. Reluctantly, the UK had adopted a defensive attitude too, striving to protect national interests through patent application, while all other participants in the project decided to continue to make their partial sequence data available without attempts at patent protection.

For the time being, this asymmetrical situation tends to inhibit international co-operation. The UK would therefore have two options: to pursue existing policy or to withdraw the patent applications. POST gave arguments for and against each option, and reminded its readers that it is probably time to harmonise international patent laws (POST, 1992).

Pros and cons were also balanced with respect to biofuels (alternatives to diesel and petrol that can be made from certain agricultural crops). POST published a note on *Biofuels for Transport* in 1993 (POST, 1993). After some technical considerations, the study reviewed arguments to judge whether biofuels are more or less environment-friendly. It also examined the European Commission policies related to the issue, primarily recent agricultural reform agreements and tax treatment.

European integration

The European integration process is fairly complex. At times, this complexity *per se* justifies a study. A good case in point was an assessment entitled *Regulating Biotechnology* (POST, 1994). POST first described the changing attitudes to regulation in Europe, as far as the genetically modified organisms were concerned. At the beginning of the 90s in the Union, two key directives were regulating the use of genetic modification and the release of modified organisms in the environment. The Contained Use Directive applied to microbial organisms and spgcified various levels of containment. The Deliberate Release Directive applied to the release of microbial organisms and of larger ones such as plants. Both required a detailed risk assessment and consent from the competent authorities (in the UK, the Health and Safety Executive and the Department of the Environment).

By the time the Directives were implemented in 1992, there were serious doubts about their appropriateness. Some questioned their consistency with up-to-date scientific thinking, and argued that the risks foreseen had been overestimated. In the UK, for instance, the directives were reviewed by the House of Lords Science and Technology Committee in 1993; it concluded that the Directives were "excessively precautionary".

The same year, a European White Paper on Growth Competitiveness and Employment concluded that biotechnology was "amongst the most vigorous and competitive sectors in the community", and the Commission was asked by the German Presidency to review the Directives in such a way as to simplify notification and consent requirements. These changes have been opposed by environmental groups who felt concerned by deregulation.

Parallel to this regulatory debate, there was growing importance attached in the Union to procedures for setting standards. The Directives' means of implementation was through the laws of Member States. This is why some variation among States took place (for instance, Germany and Denmark had introduced a stricter regime than France and Belgium which had been quite liberal). A need was felt for interpretative standards if measures were to be uniform across the Union.

The European Commission thus decided, in 1992, to commission the CEN (Centre Européen pour la Normalisation) to produce detailed standards (the CEN consists of 18 national standards bodies within the 'Old Continent'). In the formal request, the European Commission explicitly asked the CEN "to improve competitiveness in Community and external markets" (POST, 1994). Notice that POST did not itself advocate promoting biotechnologies or regulations, neither did it militate against them. It just informed.

Consensus conferences

The UK also tried something very European: a consensus conference was organised in 1994. The Danish model was mentioned, but in contrast with the Danish Board, and even more in contrast with the Dutch Rathenau Institute, POST managed to maintain a distance from the process. It just reported on it, in 1995, under the title *Plant Biotechnology - a Consensus?* (POST, 1995). The British conference was funded and organised by two agencies: one government research council (the Biotechnology and Biological Sciences Research Council) which funded the initiative; and the Science Museum which administered the event, as an organisation involved in the promotion of the public understanding of science, but without special interest in biotechnology (Joss, 1995).

In its report, POST summarised what the lay panel said. Potential benefits of plant biotechnology (such as nutritional values, reduced use of fertilisers and pesticides) were weighted against risks (such as disruption of the food chain, infringement of plant breeders' rights and undermining of traditional economies) From the consumer's perspective, the panel felt that the products were more the result of researchers and producers creating a market, rather than the market expressing a need or desire for them. On the environment, the panel noted that the impacts of plant biotechnology are difficult to predict.

Generally speaking, POST concluded that the experiment was a success. Members of the panel reported that they had learned a lot. And although consensus conferences in the UK do not have the close links to Parliament that they have in Denmark, the process gave an insight into the kinds of concerns and principles which were held by informed lay people (POST, 1995).

France

The French office of technology assessment is the oldest office in the European network, having been created at the beginning of the 80s. Yet it did not get involved in biotechnologies until the beginning of the 90s.

Agriculture and food

The fist study related to those issues dealt with the applications of biotechnologies to agriculture and food industry (OPECST, 1990). The study was requested by the parliamentary Committee of Production and Exchanges. The request came at the right time, as the introduction of the report made it clear: the European Commission had just prepared two Directives on the uses of recombinant DNA and micro-organisms, and was in the process of preparing other. The study was therefore meant to help French parliamentarians to take a stance within the Union's decision-making process. According to OPECST's rules, the report was entrusted to one of its members, who was also a Member of the Parliament.

The first question this person dealt with was: are biotechnologies really new technologies or not? Is there a revolution in that sector or simply an evolution? After a short but clear technical explanation, the analyst concluded that human beings have always contributed to natural selection since agriculture appeared on earth. In that sense, the recent development of plant improvement should not be interpreted as a revolution. Nevertheless, modern techniques, and particularly genetic engineering, lead to a real change of scale as far as selection is concerned. They also tend to suggest that humanity has a new power on life processes.

The analyst went on to describe and weight various uses of biotechnologies, their risks and benefits, for plants, for breeding, for agribusiness, for energy producing, for health sectors, for developing countries. On the whole, potential benefits were evaluated as important. Another problem was discussed at length: the patent regulation. The study was quite informative as to the history of regulations in various sectors (plants, animals, man) and in various countries; it dealt with ethical, economic and ecological stakes as well.

The study ended with a series of recommendations. It pleaded for a national debate on the issue: biotechnologies should be "demythologised and demystified" (page 85) in order to be perceived as a

The Scientific and Technological Options Assessment of the European Parliament made it clear that its role was simply to clarify the facts and arguments for or against options, but the options as such remain the responsibility of the Ministers

progress rather than a threat. In the same vein, it was suggested that information be improved in such a way as to avoid anxiety; and it was expected that scientists should communicate better about their activities. Denmark was mentioned as an example where young children get used to genetic engineering by doing some simple experiments themselves. Other recommendations dealt with improving French research in the field, getting ready to legislate on patents, studying the impact of genetic engineering on the environment, protecting genetic diversity.

Human rights

Biodiversity and Genotype's Protection was the theme of a report published in 1992.[1] The same year, OPECST dealt with another ambitious issue: life sciences and human rights (OPECST, 1992). This question was entrusted to a senator. The content was actually closer to bioethics than to regular technology assessment, insofar as it proposed great principles, and sometimes asserted normative stances, instead of simply providing information and exploring options.

The only point of agreement with the other OPECST study was the need for more information and debate. Most of the report dealt with biomedical ethics related to assisted conception, antenatal diagnoses, human body and human rights. In the introduction, it was suggested that France has a special status in the history of human rights and enlightenment, that life sciences might threaten those rights, that Europe should protect human dignity and assert great principles.

European Parliament (STOA)

STOA was launched in 1987, initially for a trial period of 18 months; then it was made permanent. To a large extent, STOA reflects the evolution of the European Parliament. The power and influence of this legislative body have slowly but surely increased (Corbett *et al*, 1997). STOA was set up, officially, to provide MEP (Members of the European Parliament) with sources of information and advice, in order to address complex scientific and technological issues.

From the very beginning, STOA made it clear that it was not its job to define Parliament's position; its role was simply to clarify the facts and arguments for or against options, but the options as such remain the responsibility of the Members. This principle of self-restraint is an important technology assessment principle. It aims to restore the rights of a political authority which a society highly dependent on science and technology seemingly denies. It seeks, as it were, to return politics to the politicians, after they have been enlightened, while stressing that it is the Members, not the experts, who have the last word. Interestingly, this principle is more clearly stated by STOA than by any national agency (except maybe the British POST). It is, however, not easy to implement, as the following examples suggest.

Bioethics

The report *Bioethics in Europe* was completed in 1992 (STOA, 1992). It aimed to provide an informed basis on important questions for legislative processes in this decade. The report presents an overview of the ethical issues raised by the new biological and genetic engineering technologies (such as human genome analysis, prenatal diagnosis, genetic screening, gene therapy, transgenic animals, patenting life forms, and economics of biotechnology), and sets out the similarities and differences between Member States in this regard.

As far as the form is concerned, the report certainly has qualities in terms of reader-friendliness: it is prefaced by an executive summary which faithfully reproduces the text and its conclusions, and permits the reader to turn quickly to the topics concerned; the topics are discussed on the basis of a similar structure (technical, ethical, social and legal aspects).

As far as the content is concerned, however, the message is somewhat ambiguous. On the one hand, the ethical assessments are not just catalogues of the values and preferences of various groups; more often than not, they seek to present "strictly moral" objections (for instance, page 95), generally on the subject of life forms, without a detailed account of what gives such objections their legitimacy. In the process, the assessors tend to think on Members' behalf, instead of simply clarifying matters so that they can make their own choices. On the other hand, after being given arguments on the potentially sacrilegious nature of various technologies, MEPs are reminded to promote the integrated market, and accordingly to foster public acceptance of biotechnologies. Hardly a coherent message.

Pharmaceuticals

From that perspective, another issue was dealt with quite differently, one year later, in a report on new pharmaceuticals substances (STOA, 1993). This analysis illustrates an important service which an assessment can perform for MEPs: to catalogue for them the issues and interests at stake in the context of a particular technological development. In this case,

there is both a technical assessment of the innovative nature of certain medicines, and an assessment of the social, economic and political implication thereof.

The study highlights both the conflicts of interest and the potential alliances; it provides some tools for mastering the complexity of the issue on both the technical and the human level. The study gives prominence to specifically European characteristics: harmonisation of national legislation (and hence, indirectly, subsidiarity), and support for the European industry in the face of the globalisation of the economy. This is no scant result, as STOA is uniquely well-positioned to analyse the distinctive European (as opposed to individual country) dimensions of the issues it addresses.

Biotechnologies and developing countries

In 1994, STOA dealt with biotechnologies and developing countries. Two reports appeared simultaneously: *Biotechnology and Cereal Production for Developing Countries* (STOA, 1994a) and *The Effect of Patent Protection on Plant Biotechnologies in Developing Countries* (STOA, 1994b). Obviously, both issues are important and relevant for MEPs; both studies highlight technical processes, and their relationship to political problems.

The first one analyses the production of maize, rice, sorghum and millet by resource-poor farmers in Sub-Saharan Africa, and the role of women, who are key actors in African farming systems. The study is aimed at helping MEPs in the context of possible restructuring of biotechnology research and development policies and budgets in the European Union.

The patent study, as well, points towards a distinctively European point of view. After explaining what a patent is, why some developing countries want patent protection and some do not, and what the international agreements on intellectual property rights are, the study sets the current European stance and the process of making directives, and amending them, by the Commission, the Council and the Parliament. The European Parliament has intervened in the process (for instance, in 1992), and recently (1998) adopted the amended Directive on patenting life, including, for instance, the "farmer's privilege" (that is, re-sowing seeds which were originally subject to patent protection).

In spite of its rather short experience, STOA seems to be catching up with its ambitious goal of helping to formulate European policies. For that matter, MEPs appear quite conscious of the potential usefulness of the agency and concerned to improve its quality (see, for instance, the evaluations recently requested: Westermeyer, 1994; Armand, 1998).

Concluding remarks

If we attempt to set the various reports mentioned above in a comparative perspective, the 'most different difference' seems to be between the 'Old' and the 'New' Continent. Even though there are some differences among the national studies from Europe (the topics they focused on, the recommendations they make), those differences are somewhat overshadowed by common features that European TA agencies share, in contrast to the American situation.

The US Congress OTA produced its main reports on biotechnologies by the end of the 80s. Not only was it the first legislative agency to deal with such a complex topic, but it dealt with it in quite an informative way for legislators. The issues were broad and varied, ranging from commercial biotechnology, international trade, changing agriculture, risk assessment, and basic research to more social, political or even philosophical problems, such as public perceptions of biotechnologies, ownership of human tissues and cells, or patenting life. This was a breakthrough as far as biotechnology assessment is concerned.

The European TA agencies did tackle the same issues, directly or indirectly, a little later, from the end of the 80s on. Yet, for the time being, the core concern underlying these studies seems to have more to do with how to promote biotechnologies without meeting too much popular resistance.

Various reasons may account for this core concern. On the one hand, the technology assessment question has been monopolised for a long time by the executive branches of the governments, the Union's administration and various academics and researchers; parliaments have been rather passive until recently and seem to be still in the learning process. On the other hand, the European Union has adopted a policy strongly promoting scientific and technological cooperation across countries since the mid-80s; such a policy is expected to help to accelerate political integration, indirectly but efficiently.

These peculiar conditions are perhaps partly responsible for some characteristics appearing in most European studies. All countries are concerned by the European Commission Directives with respect to biotechnologies and genetic engineering: all agencies give information about that matter, and most of them attempt to take a stance about the actual regulations. They share the view that it will be necessary to harmonise national legislation in the not too distant future. They look to assess national competitive advantages in that technological field, sometimes in a rather elaborate way: for instance, the Danish study on green biotechnologies, or the more recent German study on collaborating with developing countries.

Another issue which appears to be a special matter of concern for Europeans is 'social acceptance' or 'social acceptability' of biotechnologies. This might be the other side of the coin. A part of the public was, and still is, rather critical towards these techniques, especially in Germany, Denmark and the Netherlands. The fact is somewhat in conflict with the need to promote national and European industries to be competitive in the international arena. These contradictory conditions give an ambiguous flavour

to the notion of 'social acceptance': it is supposed to express a democratic concern, but it also sounds like a down-to-earth marketing device.

Within the European network, there are a few differences as well. With respect to style, for instance, the British POST displays a sense of balance and impartiality, close to the spirit pioneered by OTA ("...neither to promote nor to discourage the development of any particular technology or legislation..."). POST just strives to clarify, without taking sides, scientific and technical questions, controversies, or the complexity of the European integration process.

Consensus conferences constitute another source of difference between European TA agencies. They demonstrate the will to involve regular citizens in technological debates. The idea was pioneered by Denmark, adopted by the Netherlands and, to a lesser degree so far, by the United Kingdom. Consensus conferences have focused mainly on genetic engineering on animals and humans (predictive genetic research).

To judge their results is not an easy task. Indeed, the concept is rather ambiguous. On the one hand, it seems to surpass the democratic concern of parliamentary TA by going down to regular citizens. On the other hand, the experiences are disconcerting and challenge precisely this good intention. More often than not, popular juries express authoritarian views (for instance, lay panels requesting that ethicists control fundamental genetic research, without clearly defining who ethicists are supposed to be and what is the basis for the legitimacy of their decisions).

In addition, the legitimacy of the lay panel's opinions may be questioned, as it is neither elected nor statistically representative of the society, especially when the consensus conference has an impact on a political decision (for instance, the Danish Parliament decided not to fund animal gene technology projects in the biotechnology research and development programme 1987–1990, as a consequence of the 1987 conference).

Notes

1. This report was no longer available at the time of this research.

References

J L Armand (1998), *Advice on the Quality Management of Technology Assessment Reports* (European Parliament, Strasbourg).

B Bimber (1996), *The Politics of Expertise in Congress* (State University of New York Press, NY).

R Corbett *et al* (1997), *The European Parliament* (Longman, London).

DBT, Danish Board of Technology (1987), *Genetic Technology in Industry and Agriculture*, Consensus Conference, 25–27April.

DBT, Danish Board of Technology (1989), *Application of Knowledge gained from Mapping the Human Genome*, Consensus Conference, 1–3 November.

DBT, Danish Board of Technology (1991), *Research and Development in Danish Biotechnology* (Danish Board of Technology, Copenhagen, Project Publication no 6/91).

DBT, Danish Board of Technology (1992a), *Biotechnology in the Environmental Field* (Danish Board of Technology, Copenhagen, Project Publication no 1/92).

DBT, Danish Board of Technology (1992b), *Technological Animals*, Consensus Conference, 23–25 September.

DBT, Danish Board of Technology (1993), *Projects at the Danish Board of Technology* (Danish Board of Technology, Copenhagen, Catalogue, October).

European Congress on Technology Assessment (1992), *Technology and Democracy*, Proceedings of the 3rd European Congress on Technology Assessment (European Congress on Technology Assessment, Copenhagen).

F Gloede (1992), "Biological safety in the use of genetic engineering", in European Congress on Technology Assessment (1992), pages 273–278.

F Gloede (1997), *Technology Assessment of Gene Therapies in Germany* (Johns Hopkins Oncology Center, Baltimore).

S Joss (1995), "Evaluating consensus conferences: necessity or luxury?", in Joss and Durant (1995).

S Joss and J Durant (editors) (1995), *Public Participation in Science* (Science Museum, London and European Commission Directorate General XII, Brussels).

L Klüver (1995), "Consensus conferences at the Danish Board of Technology", in Joss and Durant (1995).

I Mayer *et al* (1995), "An evaluation of the effects of participation in a consensus conference", in Joss and Durant (1995).

C Mironesco (1997), *Un enjeu démocratique: Le Technology Assessment. Maîtrise de la technologie aux Etats-Unis et en Europe* (Georg, Genève).

NOTA, Netherlands Organisation for Technology Assessment (1990), *Het maakbare dier. Ethiek en transgene dieren* (NOTA, The Hague).

NOTA, Netherlands Organisation for Technology Assessment (1991a) *Levende uitvindingen* (NOTA, The Hague).

NOTA, Netherlands Organisation for Technology Assessment (1991b), *Discussie over genetisch gemodificieerde organismen in het milieu* (NOTA, The Hague).

NOTA, Netherlands Organisation for Technology Assessment (1992a), *Regulation and Discussion on Genetic Modification of Animals* (NOTA, The Hague).

NOTA, Netherlands Organisation for Technology Assessment (1992b), *Ethiek, politiek en genetische modificatie van dieren* (NOTA, The Hague).

NOTA, Netherlands Organisation for Technology Assessment (1992c), *Biotechnologie en kleinschalige landbouw in ontwikkelingslanden* (NOTA, The Hague).

NOTA, Netherlands Organisation for Technology Assessment (1993a), *Public Debate. Genetic Modification of Animals, should it be allowed?* (NOTA, The Hague).

NOTA, Netherlands Organisation for Technology Assessment (1993b), *Het maakbare dier geregeld* (NOTA, The Hague).

OPECST, Office Parlementaire d'Evaluation des Choix Scientifiques et Technologiques (1990), *Rapport sur les applications des biotechnologies à l'agriculture et à l'industrie agro-alimentaire* (Assemblée Nationale, Paris, Report by Daniel Chevallier, Député).

OPECST, Office Parlementaire d'Evaluation des Choix Scientifiques et Technologiques (1992), *Sciences de la vie et droits de l'homme. Bouleversements sans contrôle ou maîtrise parlementaire d'une évolution?* (Assemblée Nationale, Paris, report by Franck Serusclat, Sénateur).

OTA, Office of Technology Assessment (1984), *Commercial Biotechnology: An International Perspective* (US Government Printing Office, Washington, DC).

OTA, Office of Technology Assessment (1987a), *New Developments in Biotechnology Series (Vol. 1) Ownership of Human Tissues and Cells* (US Government Printing Office, Washington, DC).

OTA, Office of Technology Assessment (1987b), *New Developments in Biotechnology Series (Vol 2) Public Perceptions of Biotechnology* (US Government Printing Office, Washington, DC).

OTA, Office of Technology Assessment (1988a), *New Developments in Biotechnology Series (Vol 3) Field-Testing Engineered Organism* (US Government Printing Office, Washington, DC).

OTA, Office of Technology Assessment (1988b), *New Developments in Biotechnology Series (Vol 4) U.S. Investment in Biotechnology* (US Government Printing Office, Washington, DC).

OTA, Office of Technology Assessment (1988c), *New Developments in Biotechnology Series (Vol. 5) Patenting Life* (US Government Printing Office, Washington, DC).
OTA, Office of Technology Assessment (1988d), *Mapping Our Genes* (US Government Printing Office, Washington, DC).
OTA, Office of Technology Assessment (1993a), *Justification of Estimates* (US Government Printing Office, Washington, DC).
OTA, Office of Technology Assessment (1993b), "Biomedical ethics in U.S. public policy — background paper" (US Government Printing Office, Washington, DC).
OTA, Office of Technology Assessment, (1993c), *Policy Analysis at OTA* (US Government Printing Office, Washington, DC) page 54.
L C Plein and D Webber (1992), "The role of technology assessment in congressional consideration of biotechnology", in G Bryner (editor), *Science, Technology and Politics. Policy Analysis in Congress* (Westview, Boulder).
POST, Parliamentary Office of Science and Technology (1991), "Patenting life", Briefing Note no 26, June.
POST, Parliamentary Office of Science and Technology (1992), "Patenting human DNA", Briefing Note no 37, November.
POST, Parliamentary Office of Science and Technology (1993), "Biofuels for transport", Briefing Note no 41, March.
POST, Parliamentary Office of Science and Technology (1994), "Regulating biotechnology", Briefing Note no 55, November.
POST, Parliamentary Office of Science and Technology (1995), "Plant biotechnology. A consensus?", Briefing Note no 56, January.
Rathenau Institute (1994), *Work Programme Rathenau Institute 1995–1996* (Rathenau Institute, The Hague).
Rathenau Institute (1995a), *The Rathenau Institute and the Debate*, Annual Report 1994 (Rathenau Institute, The Hague).
Rathenau Institute (1995b), "Predictive genetic research, where are we going?", Report to Parliament, April.
Rathenau Institute (1995c), "Lerend innoveren. Maatschappelijke inbedding van nieuwe biotechnologie", Report to Parliament.
Rathenau Institute (1995d), *Biotechnologie in bedrijf. Een bijdrage van Constructief Technology Assessment aan biotechnologisch innoveren*, Study no 29.
Science Museum (1992), *Biotechnology in Public. A review of recent research* Science Museum for the European Federation of Biotechnology, London).
L Sterrenberg (1993a), "The Netherlands Organization of Technology Assessment", workshop at Parliamentary Technology Assessment. European Experiences conference, Vienna, 19 October.
L Sterrenberg (1993b), "Ethical issues in modern biotechnology for agriculture and fisheries. Dutch experience", paper presented at Meeting of Nent, Oslo, 10–11 November.
STOA, Scientific and Technological Options Assessment (1992), *Bioethics in Europe* (European Parliament, STOA, Luxemburg).
STOA, Scientific and Technological Options Assessment (1993), *New Pharmaceuticals Substances* (European Parliament, STOA, Luxemburg).
STOA, Scientific and Technological Options Assessment (1994a), *Biotechnology and Cereal Production for Developing Countries* (European Parliament, STOA, Luxembourg).
STOA, Scientific and Technological Options Assessment (1994b), *The Effects of Patent Protection on Plant Biotechnologies in Developing Countries* (European Parliament, STOA, Luxemburg).
TAB, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (1993a), "Genetic mapping".
TAB, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (1993b), "Technikfolgen-Abschätzung zu neuen Biotechnologien. Auswertung ausgewählter Studien ausländische parlamentarischer TA-Einrichtungen", TAB Arbeitsbericht no 19, Bonn.
TAB, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (1993c), "Scientific and medical state-of-the-art in the development of genetic therapeutic methods".
TAB, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (1994a), "Ist die (deutsche) Öffentlichkeit 'technikfeindlich'?", TAB Arbeitsbericht no 24, Bonn.
TAB, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (1994b), "Stand und Perspektiven naturwissenschaftlicher und medizinischer Problemlösungen bei der Entwicklung gentherapeutischer Heilmethoden", TAB Arbeitsbericht no 25, Bonn.
TAB, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (1995), "Auswirkungen moderner Biotechnologien auf Entwicklunsländer und Folgen für die zukunftige Zusammenarbeit zwischen Industrie- und Entwicklungsländern, TAB-Arbeitsbericht no 34, Bonn.
TAB, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (1996), "Monitoring Gentherapie. Die rechtliche Regelung der Gentherapie im Ausland", TAB Arbeitsbericht no 40, Bonn.
W Westermeyer (1994), *An Evaluation of the Scientific and Technological Options Assessment Programme (STOA)* (European Parliament, Luxemburg).
E J Woodhouse (1992), "Toward more usable technology policy analyses", in G Bryner (editor), *Science, Technology and Politics*, (Westview, Boulder).